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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,063	03/02/2004	Yoshinobu Kohara	H&A-126	9823

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EXAMINER	
CROW, ROBERT THOMAS	
ART UNIT	PAPER NUMBER
1634	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/790,063	KOHARA ET AL.	
	Examiner	Art Unit	
	Robert T. Crow	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

FINAL ACTION

Status of the Claims

1. This action is in response to papers filed 26 October 2006 in which claims 1-2, 5-10, and 13 were amended, claims 14-18 were canceled, and no new claims were added. All of the amendments have been thoroughly reviewed and entered.

The examiner has considered documents 2000-346842 (Japan), 2002-117487 (Japan), and 11/243997 (Japan). A newly initialed Information Disclosure Statement is provided. The three non-patent literature citations were previously considered, and have been lined through to avoid duplication.

The previous rejections under 35 U.S.C. 112, second paragraph, are withdrawn in view of the amendments.

The previous rejections under 35 U.S.C. 102(b) and 35 U.S.C. 103(a) not reiterated below are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed and are addressed following the rejections necessitated by the amendments.

Claims 1-13 are under prosecution.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-4, 7-8, and 10-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Burd Mehta et al (PCT International Application Publication No WO 00/50172, published 31 August 2000).

Regarding claim 1, Burd Mehta et al teach a microparticle array analyzing system. In a single exemplary embodiment, Burd Mehta et al teach a vessel in the form of channel region 415 of a

microfluidic device of Figure 3A(page 22, line 29-page 24, line 133). Burd Mehta et al teach a magnetic particle is used to create a particle retention region for non-magnetic particles in the channel (page 31, lines 7-19). The vessel therefore holds a magnetic and a non-magnetic particle arranged therein in a given sequence. The particles have samples thereon (page 4, lines 5-22); the vessel thus receives the sample because it is on the particle. Burd Mehta et al further teach a magnet member disposed proximal to the channel, and thus outside the vessel, for magnetically controlling the position of the magnetic particles with respect to the vessel (page 22, line 29-page 23 line 10).

Regarding claim 2, Burd Mehta et al teach the system of claim 1, wherein the vessel holds first a second magnetic microparticles; namely, the stacking of multiple sets of different particles withing the channel (page 29, lines 10-31), and that subsequent sets of particles are smaller magnetic particles (page 31, lines 7-19). Thus, the first layer of magnetic particles are the particle retention region of claim 1, which is followed by the layer of non-magnetic particles of claim 1, which have fixed nucleic acid probes thereon (page 4, lines 5-22). The third layer is the set of smaller magnetic particles (page 31, lines 7-19).

Regarding claim 3, Burd Mehta et al teach the system of claim 1, wherein a plurality of magnetic microparticles are used ; namely, a magnetic particle set is used to retain the non-magnetic particles (page 31, lines 7-19 and Figure 14). Burd Mehta et al also teach the non-magnetic particle sets have fixed nucleic acid probes thereon (page 4, lines 5-22).

Regarding claim 4, Burd Mehta et al teach the system of claim 2, further comprising a detector and an analyzer in the form of a computer (Figure 12).

Regarding claim 7, Burd Mehta et al teach the system of claim 1, wherein the vessel has branched channels inside; namely, the channel region is a microscale cavity having a microchannel network (page 3, lines 17-25), wherein the array members, which are the particles, are stored in an integrated external storage element and fluidically transferred to the channel region (page 89, lines 5-24).

In addition, the courts have held that "while features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in

terms of structure rather than function." *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997). In addition, "[A]pparatus claims cover what a device *is*, not what a device *does*." *Hewlett-Packard Co. v. Bausch &Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (emphasis in original). Therefore, the various uses recited in claim 7 (e.g., taking particles out of a channel) fail to define additional structural elements to the device. Because Burd Mehta et al teach the structural elements of claim 7, the claim is anticipated by Burd Mehta et al. See MPEP § 2114.

Regarding claim 8, Burd Mehta et al teach the system of claim 1, further comprising a combination of magnetic and electrophoretic transport systems within the microfluidic device (page 15, line 30-page 17, line 8). The magnetic and non-magnetic particles are therefore taken out of an opening end of vessel 415 of Figure 3A and transported through an electrophoresis channel (page 17, lines 1-29), which is the transport mechanism connected to the electrophoresis apparatus.

Regarding claims 10-13, Burd Mehta et al teach a microarray particle kit (page 96, lines 10-30). In a single exemplary embodiment, Burd Mehta et al teach kits comprising a vessel in the form of a channel of a microfluidic device (page 22, line 29-page 23 line 10). Burd Mehta et al teach a magnetic particle is used to create a particle retention region for non-magnetic particles in the channel(page 31, lines 7-19). The vessel therefore holds a magnetic and a non-magnetic particle arranged therein in a given sequence. The particles have samples thereon (page 4, lines 5-22); the vessel thus receives the sample because it is on the particle. Burd Mehta et al further teach a magnet member proximal to the channel, and thus disposed outside the vessel, for magnetically controlling the position of the magnetic particles with respect to the vessel (page 22, line 29-page 23 line 10). Burd Mehta et al also teach the non-magnetic particle sets have fixed nucleic acid probes thereon (page 4, lines 5-22). The particles are in the vessel, and the probes are therefore in the vessel as well.

Burd Mehta et al further teach the probe is immobilized to a particle set (page 4, lines 5-22), wherein the particle sets comprise either magnetic or non-magnetic particles (page 4, lines 5-22). Burd Mehta et al also teach the vessel is a channel in a substrate (page 3, lines 17-25).

4. Claims 1-2, 4-5, 8, 10-11, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Hauser et al (PCT International Application Publication No. WO 99/60170, published 25 November 1999).

Regarding claim 1, Hauser et al teach a microparticle array analyzing system. In a single exemplary embodiment, Hauser et al teach Figure 1, which shows a vessel in the form of tube 12 containing a linear array of beads 18 and 20 (page 9, lines 10-26). The vessel 12 accepts solutions of target analytes, which is a sample (page 9, lines 10-26). Hauser et al further teach the beads are glass beads (page 13, lines 19-30), which are non-magnetic microparticles. Hauser et al also teach magnetic microparticles (i.e., beads) are placed at the ends of the linear array, and that a magnet member in the form of a hand magnet is disposed outside of the vessel for magnetically controlling the positions of the particles in the vessel (page 19, lines 1-5). The microparticles are arranged in a given sequence because the glass microparticles are in between the terminal magnetic microparticles.

It is noted that the specification does not provide a limiting definition of a "system." Thus, the "system" is interpreted to encompass any collection of reagents and parts used together that are not necessarily part of a completely integrated single unitary device. Any further interpretation of the word is considered an "intended use" and does not impart any further structural limitation on the claimed subject matter.

Regarding claim 2, Hauser et al teach the system of claim 1, wherein the vessel holds first and second magnetic microparticles; namely, the terminal magnetic microparticles at both ends of the array (page 19, lines 1-5). Hauser et al also teach non-magnetic microparticles have probe 22 attached (page 9, lines 10-26). Because the magnetic microparticles are at the termini, the non-magnetic microparticles are sandwiched between the first and second magnetic microparticles.

Regarding claim 4, Hauser et al teach the system of claim 2, further comprising a detector in the form of a CCD device and an analyzer in the form of a densitometer (page 21, lines 6-28).

Regarding claim 5, Hauser et al teach the system of claim 1, wherein the magnet is movably provided outside the vessel; namely, the magnet is a hand magnet for oscillating the magnetic field (page 19, lines 1-5).

Regarding claim 8, Hauser et al teach the system of claim 1, further comprising a transport mechanism; namely, a pressurized airflow pump (page 22, lines 26-30) and that beads are removed from the linear array through an opening end of the vessel (page 23, lines 1-13). Hauser et al also teach that an electrophoresis apparatus is connected to the transport mechanism; namely, the device has electrophoretic and mechanical pumps (page 20, lines 13-15).

Regarding claims 10-11, Hauser et al teach a microparticle array kit. In a single exemplary embodiment, Hauser et al teach Figure 1, which shows a vessel in the form of tube 12 containing a linear array of beads 18 and 20 (page 9, lines 10-26). The vessel 12 accepts solutions of target analytes, which is a sample (page 9, lines 10-26). Hauser et al further teach the beads are glass beads (page 13, lines 19-30), which are non-magnetic microparticles. Hauser et al also teach non-magnetic microparticles have probe 22 attached (page 9, lines 10-26). The particles are in the vessel, and the probes are therefore in the vessel as well. Hauser et al also teach magnetic microparticles (i.e., beads) are placed at the ends of the linear array, and that a magnet member in the form of a hand magnet is disposed outside of the vessel for magnetically controlling the positions of the particles in the vessel (page 19, lines 1-5). The microparticles are arranged in a given sequence because the glass microparticles are in between the terminal magnetic microparticles.

It is noted that the specification does not provide a limiting definition of a "kit." Thus, the "kit" is interpreted to encompass any collection of reagents or structures that includes all of the elements of the claims. Any further interpretation of the word is considered an "intended use" and does not impart any further structural limitation on the claimed subject matter.

Regarding claim 13, Hauser et al teach the kit of claim 10, wherein the vessel is a channel in a capillary; namely, the microparticles are contained within a capillary tube (page 6, lines 28-31).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1 and 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burd Mehta et al (PCT International Application Publication No WO 00/50172, published 31 August 2000) in view of ~~Southgate et al (U.S. Patent No. 5,863,502, issued 26 January 1999).~~

Regarding claims 5-6, Burd Mehta et al teach the microparticle array analyzing system of claim 1. In an exemplary alternate embodiment from that presented under 35 U.S.C. 102(b) above, Burd Mehta et al teach a vessel in the form of a microfluidic device (page 22, line 29-page 23 line 10). Burd Mehta et al teach a magnetic particle is used to create a particle retention region for non-magnetic particles in a channel of the device (page 31, lines 7-19). The vessel therefore holds a magnetic and a non-magnetic particle arranged therein in a given sequence. The particles have samples thereon (page 4, lines 5-22); the vessel thus receives the sample because it is on the particle.

Burd Mehta et al also teach a magnet member disposed outside the vessel for magnetically controlling the position of the magnetic particles with respect to the vessel (page 22, line 29-page 23 line 10) and that the magnetic filed is moved relative to the particles (i.e., array members; page 89, lines 5-11). While Burd Mehta et al also teach the magnet is an electromagnet (page 20, lines 1-8), Burd Mehta et al do not explicitly teach the magnet itself is movable.

However, Southgate et al teach a system comprising fluidic channels (Abstract and Figure 16) having movable magnet 1100 outside a reaction chamber (i.e., channel) for moving magnetic beads and having the added advantage that the motility of the magnet allows the field gradient acting upon the beads to be maximized (column 25, line 49-column 26, line 16).

It would therefore have been obvious to a person or ordinary skill in the art at the time the invention was claimed to have modified the system comprising movement of magnetic fields generated by electromagnets as taught by Burd Mehta et al with the movable magnet as taught by Southgate et al with a reasonable expectation of success. The ordinary artisan would have been motivated to make such a modification because said modification would have resulted in allowing the field gradient acting upon the beads to be maximized as explicitly taught by Southgate et al (column 25, line 49-column 26, line 16).

8. Claims 1 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burd Mehta et al (PCT International Application Publication No WO 00/50172, published 31 August 2000) in view of Harrison et al (U.S. Patent No. 6,432,290 B1, issued 13 August 2002).

Regarding claim 9, Burd Mehta et al teach the microparticle array analyzing system of claim 1. In a single exemplary embodiment, Burd Mehta et al teach a vessel in the form of channel region 415 of a microfluidic device of Figure 3A(page 22, line 29-page 24, line 133). Burd Mehta et al teach a magnetic particle is used to create a particle retention region for non-magnetic particles in the channel (page 31, lines 7-19). The vessel therefore holds a magnetic and a non-magnetic particle arranged therein in a given sequence. The particles have samples thereon (page 4, lines 5-22); the vessel thus receives the sample

because it is on the particle. Burd Mehta et al further teach a magnet member disposed proximal to the channel, and thus outside the vessel, for magnetically controlling the position of the magnetic particles with respect to the vessel (page 22, line 29-page 23 line 10).

Burd Mehta et al also teach the system further comprises a combination of magnetic and non-magnetic transport systems within the microfluidic device (page 15, line 30-page 17, line 8). The magnetic and non-magnetic particles are therefore taken out of an opening end of vessel 415 of Figure 3A and transported through another channel (page 17, lines 1-29), which is the transport mechanism.

Burd Mehta et al also teach While Burd Mehta et al also teach downstream detection is performed by mass spectrometry (page 55, lines 1-13), Burd Mehta et al do not explicitly teach the mass spectroscope is connected to the transport mechanism; i.e., fluidically integrated with the device.

However, Harrison et al teach a vessel comprising channels (Figure 10) and having a transport mechanism for collecting the microparticles from an opening end of the vessel; namely, microparticles in the form of beads (Abstract) are fluidically pumped through an electrospray coupler to a mass spectrometer (Figure 10 and column 18, lines 7-25)) with the added advantage that an integrated system eliminated sample handling losses and contamination problems arising from off-device (i.e., off-chip) sample manipulation (column 4, lines 25-35).

It would therefore have been obvious to a person or ordinary skill in the art at the time the invention was claimed to have modified the system comprising transport of microparticles and mass spectrometry as taught by Burd Mehta et al with the fluidic integration of the device as taught by Harrison et al with a reasonable expectation of success. The ordinary artisan would have been motivated to make such a modification because said modification would have resulted in a system that eliminates sample handling losses and contamination problems arising from off-device as explicitly taught by Harrison et al (column 4, lines 25-35).

Response to Arguments

9. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

10. No claim is allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

12. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert T. Crow whose telephone number is (571) 272-1113. The examiner can normally be reached on Monday through Friday from 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Robert T. Crow
Examiner
Art Unit 1634

RAM R. SHUKLA, PH.D.
SUPERVISORY PATENT EXAMINER